REMARKS/ARGUMENTS

Claim Objections

Claims 1, 4, and 5 were objected for various reasons. Specifically, claims 1 and 4 were objected to for including non-elected subject matter. The Examiner's objection is moot in light of the amendments made herein (*infra*). Further, claim 5 was objected for a typographical error. The applicant agrees and corrected claim 5 accordingly.

35 USC § 112, first paragraph

Claims 1 and 5 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states in the office action that the claim would be drawn to subject matter which was allegedly not adequately described in the specification. The applicant respectfully disagrees. Nevertheless, and only for the purpose of advancing prosecution in this matter, the ***applicant limited the scope of the glypican-1-binding molecule to those disclosed in the specification***. Thus, amended claims 1 and 5 should not be rejected under 35 USC § 112, first paragraph.

35 USC § 102 (b)

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 32133-3222 (1994)). The applicant disagrees, especially in view of the amendments made herein.

As amended, claim 1 expressly requires the diagnostic agent to be an "***agent for detection of at least one of human breast cancer and pancreatic cancer***", and that the reporting molecule is attached to the binding molecule "***such that a detection method allows detection of the cancer by detection of the presence of the binding molecule via detection of the reporting molecule***". It should be noted that the preamble and further elements of the claims as amended provide specific life and meaning to the subject matter for which protection is being sought, and not just merely attempt to recite an intended use (*e.g.*, Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) "...[W]hen the claim drafter chooses to use both the preamble and the body to define the subject matter of

the claimed invention, the invention so defined, and not some other, is the one the patent protects...", or Pitney Bowes, 182 F.3d at 1306: "...Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope...").

In contrast, Karthikeyan et al. describe compositions and methods for detection of rat glypican in various non-cancerous neuronal tissues, which is entirely inconsistent with the presently pending subject matter of claims 1-4. Therefore, amended claims 1-4 should not be deemed anticipated by Karthikeyan et al.

With respect to claims 5-6, the Examiner stated that Karthikeyan's antibody "would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1". It is ***unclear to the applicant how an antibody would have hydrolytic properties as apparently asserted by the Office***. While catalytic antibodies are known in the art, Karthikeyan's antibody are clearly not of such type as these antibodies were raised using a synthetic peptide and not a transition state analog for a hydrolytic reaction of glypican-1. Attachment of HRP will not remedy this defect. Furthermore, and with respect to the ***expressly claimed property of slowing growth of a human breast cancer and/or pancreatic cancer cell***, the same considerations and arguments as provided above apply.

Still further, the Examiner appears to assert that the antibody of Karthikeyan et al. would correspond to an antibody against human glypican-1. However, ***it is not clear how the Office could properly arrive at such conclusionary statement on the basis of the cited reference.*** Among other things, and as specifically discussed in the background section and other publications, there are numerous and structurally distinct glypican molecules within the glypican family. Absent specific teachings in the reference that the peptide would correspond to the human glypican-1, anticipation cannot be properly established. Even more significantly, the presently pending claims are directed to human glypican-1, which is again inconsistent with the reference's glypican. Therefore, and at least for the above reasons, amended claims 1-6 should not be deemed anticipated by Karthikeyan et al.

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Claims 1-6 were further rejected under 35 USC § 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332 (1997)). The applicant again disagrees, especially in view of the amendments made herein.

As above, amended claim 1 specifically requires the diagnostic agent to be an "***agent for detection of at least one of human breast cancer and pancreatic cancer***", and that the reporting molecule is attached to the binding molecule "***such that a detection method allows detection of the cancer by detection of the presence of the binding molecule via detection of the reporting molecule***".

In contrast, Ivins et al. teach compositions and methods for detection of cerebroglycan in various non-cancerous rat neuronal tissues, which is once more entirely inconsistent with the presently pending subject matter of claims 1-4 (*supra*). Therefore, amended claims 1-4 should not be deemed anticipated by Ivins et al.

With respect to claims 5-6, the Examiner stated that Ivins' antibody "would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1". Again, it is ***unclear to the applicant how an antibody would have hydrolytic properties as apparently asserted by the Office***. Attachment of Cy-3 will not remedy this defect. Furthermore, and with respect to the ***expressly claimed property of slowing growth of a human breast cancer and/or pancreatic cancer cell***, the same considerations and arguments as provided above apply.

As pointed out above, the Examiner seems to assert that the antibody of Ivins et al. would correspond to an antibody against glypican-1. However, ***it is again not clear how the Office could properly arrive at such conclusionary statement on the basis of the cited reference*** as there are numerous and structurally distinct glypican molecules within the glypican family. Absent specific teachings by Ivins et al. that their peptide would correspond to the human glypican-1, anticipation cannot be properly established. Furthermore, the presently pending claims are directed to human glypican-1, which is inconsistent with the reference's glypican. Therefore, and at least for the above reasons, amended claims 1-6 should not be deemed anticipated by Ivins et al.

35 USC § 102 (a)

Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864 (1997)). The applicant again disagrees, especially in view of the amendments made herein.

As above, amended claim 1 specifically requires the diagnostic agent to be an "***agent for detection of at least one of human breast cancer and pancreatic cancer***", and that the reporting molecule is attached to the binding molecule "***such that a detection method allows detection of the cancer by detection of the presence of the binding molecule via detection of the reporting molecule***".

In contrast, Liang et al. teach compositions and methods for detection of glypican and/or biglycan in various non-cancerous rat neuronal tissues, which is entirely inconsistent with the presently pending subject matter of claims 1-4. Therefore, amended claims 1-4 should not be deemed anticipated by Liang et al.

With respect to claims 5-6, the Examiner stated that Liang's antibody would "cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1". First, ***Liang expressly teaches nuclear detection*** (see e.g., Figures 11 and 13, discussion page 862, right column, paragraph starting with "the glypican and biglycan...") of the glypican, which is in stark contrast to the detection asserted by the Examiner. Second, it is again ***unclear to the applicant how an antibody would have hydrolytic properties as apparently asserted by the Office***. Third, the ***antibody in the cited reference is detected with a secondary labeled antibody***, which is once more inconsistent with the presently claimed subject matter. Finally, and with respect to the ***expressly claimed property of slowing growth of a human breast cancer and/or pancreatic cancer cell***, the same considerations and arguments as provided above apply.

Once more, and as already pointed out above, the Examiner seems to assert that the antibody of Liang et al. would correspond to an antibody against glypican-1. However, ***it is not clear how the Office could properly arrive at such conclusionary statement on the basis of the cited reference*** as there are numerous and structurally distinct glypican molecules within the glypican family. Absent specific teachings by Liang et al. that their peptide would correspond to

the human glypican-1, anticipation cannot be properly established. Moreover, the presently pending claims are directed to human glypican-1, which is again inconsistent with the reference's glypican. Therefore, and at least for the above reasons, amended claims 1-6 should not be deemed anticipated by Liang et al.

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Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87 (1998)). The applicant once more disagrees, especially in view of the amendments made herein.

Amended claim 1 specifically requires the diagnostic agent to be an "***agent for detection of at least one of human breast cancer and pancreatic cancer***", and that the reporting molecule is attached to the binding molecule "***such that a detection method allows detection of the cancer by detection of the presence of the binding molecule via detection of the reporting molecule***".

In contrast, Litwack et al. teach compositions and methods for detection of glypican-1 in various non-cancerous rat tissues (neuronal and others), which is once more entirely inconsistent with the presently pending subject matter of claims 1-4 (*supra*). Therefore, amended claims 1-4 should not be deemed anticipated by Litwack et al.

With respect to claims 5-6, the Examiner stated that Litwack's antibody would "cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1". It is ***unclear to the applicant how an antibody would have hydrolytic properties as apparently asserted by the Office***. Moreover, with respect to the ***expressly claimed property of slowing growth of a human breast cancer and/or pancreatic cancer cell***, the same arguments and considerations as provided above apply. Therefore, amended claims 5-6 should not be deemed anticipated by Litwack et al.

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Claims 1-6 were rejected under 35 USC § 102(b) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832 (1998)). The applicant again disagrees, especially in view of the amendments made herein.

Again, amended claim 1 specifically requires the diagnostic agent to be an "***agent for detection of at least one of human breast cancer and pancreatic cancer***", and that the reporting molecule is attached to the binding molecule "***such that a detection method allows detection of the cancer by detection of the presence of the binding molecule via detection of the reporting molecule***".

In contrast, Liu et al. teach compositions and methods for Western and dot blot detection of glypican-1. Such method is entirely inconsistent with the presently pending subject matter of claims 1-4 (*supra*). Therefore, amended claims 1-4 should not be deemed anticipated by Liu et al.

With respect to claims 5-6, the Examiner again stated that Liu's antibody would "cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1". It is ***unclear to the applicant how an antibody would have hydrolytic properties as apparently asserted by the Office*** (*supra*). Moreover, with respect to the ***expressly claimed property of slowing growth of a human breast cancer and/or pancreatic cancer cell***, the same considerations and arguments as provided above apply. Therefore, amended claims 5-6 should not be deemed anticipated by Liu et al.

REQUEST FOR ALLOWANCE

Claims 1-6 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,

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